EXHIBIT C

United States Food and Drug Administration
Consumer Complaint / Injury Report

This is an accurate reproduction of the original electronic record as of 06/07/2016

COMPLAINT # 131097

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
03/07/2013	NWE-DO	LOS-DO	Telephone	Industry	Vantwuyver,Sheila M	Closed

Complainant Identification

Name	Address
anonymous	MA

Phone (W)	Phone (H)	Source POC Name	Source Phone

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
Complainant reported a problem with Bard's vena cava filters, labeled as G2 filters, manufactured between 2004 - 2008. Complainant knows of 1000 adverse events not reported to FDA. Complaints involve breakages, migrations, and perforations that resulted in serious injuries.	None		

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
No		N/A	N/A	N/A	Unknown	Unknown

Remarks
The G2 was manufactured in Tempe, AZ and firm's corporate HQ is in Murray Hil, NJ. Details were provided in a memo of telecon written by NWE-DO's Compliance Officer. Memo of telecon is attached with the complaint record.

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks

Health Care Professional

Provider Name	Address	Phone	Occupation

Hospital Information

Hospital Name	Address	Phone	Dates of Stay

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date

Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
Bard	vena cava filters, G2	74	Cardiovascular	81R801	

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Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
				No	

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
			No		

Retail

Problem Ingredient Group

Name	Address
n/a	

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
2020394	Bard Peripheral Vascular Inc 1625 W 3rd St Tempe Arizona United States 85281-2438	LOS-DO	Manufacturer
1000208905	C. R. Bard, Inc. 730 Central Ave New Providence New Jersey United States 07974-1139	NWJ-DO	Corporate Headquarters

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Other, identify in Details	Firm not reporting 1000 adverse events and serious injuries to FDA

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	Referred to Other FDA District	Vantwuyver,Sheila M	03/07/2013

Initial Disposition Remarks

NWJ-DO, LOS-DO, and CDRH were notified. CC was referred to NWJ-DO first.
NWJ CCC discussed complaint with Deputy DD who instructed her to forward complaint to LOS-DO, location of manufacturer.

Referrals

Org Name	HHS Mail Code
NWJ-DO	HFR-MA300
LOS-IB-CCC	HFR-PA250T

There are no Cosmetics details for this Complaint.

There are no Adverse Event details for this Complaint.

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COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date

There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type

Follow-Up Disposition	Disposition Made By	Disposition Date
Surveillance Information for Next EI	Lee,Franklin	03/27/2013

Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code
LOS-DO	HFR-PA200